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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.  | CONFIRMATION NO. |
|--|-------------|----------------------|----------------------|------------------|
| 10/848,922   | 05/18/2004  | William G. Weisburg  | GP142-02.UT          | 5696             |
| 21365  | 7590        | 06/21/2007           | EXAMINER             |                  |
| GEN PROBE INCORPORATED<br>10210 GENETIC CENTER DRIVE<br>Mail Stop #1 / Patent Dept.<br>SAN DIEGO, CA 92121 |             |                      | NAVARRO, ALBERT MARK |                  |
|  |             |                      | ART UNIT             | PAPER NUMBER     |
|  |             |                      | 1645                 |                  |
|  |             |                      | NOTIFICATION DATE    | DELIVERY MODE    |
|  |             |                      | 06/21/2007           | ELECTRONIC       |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentdept@gen-probe.com  
kelleec@gen-probe.com  
belindao@gen-probe.com

|                              |                        |                     |
|------------------------------|------------------------|---------------------|
| <b>Office Action Summary</b> | <b>Application No.</b> | <b>Applicant(s)</b> |
|                              | 10/848,922             | WEISBURG ET AL.     |
|                              | <b>Examiner</b>        | <b>Art Unit</b>     |
|                              | Mark Navarro           | 1645                |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) Responsive to communication(s) filed on 16 April 2007.  
 2a) This action is FINAL.                    2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) Claim(s) 81-131 is/are pending in the application.  
 4a) Of the above claim(s) 94 and 111 is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 81-93,95-110 and 112-131 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____. _____   | 6) <input type="checkbox"/> Other: _____                          |

**DETAILED ACTION**

Applicants amendment filed April 16, 2007 has been received and entered.

Claims 1-80 have been cancelled and new claims 81-131 have been added.

Consequently, claims 81-131 are pending in the instant application, of which claims 94, and 111 are withdrawn from further consideration as being drawn to non-elected method claims.

***Claim Rejections - 35 USC § 112***

1. The rejection of claims 1-19, 21-38 and 77-80 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, a written description rejection is maintained as applied to newly added claims 81, 85, 87-93, 95-99, 106-110, 112, 115-117, 120-123, 130 and 131.

Applicants are asserting that the claims have been amended to distinguish the attributes of the claimed probes as being the sequence of the target binding region. Applicants further assert that the structural identities of the probes plus a functional requirement (hybridize to nucleic acid derived from *T. vaginalis* but not *T. tenax*) are set forth.

Applicants arguments have been fully considered but are not found to be fully persuasive.

First, Applicants assert that the claims have been amended to distinguish the

attributes of the claimed probes as being the sequence of the target binding region. It is noted that claims which recite "consisting of" the particular sequence are deemed to satisfy the written description requirement. However, claims reciting "comprising" or "having" the sequence are still deemed to not satisfy this requirement. Specifically, the disclosed function of the probe, being able to bind to *T. vaginalis* but not from *T. tenax*, is inextricably dependent upon the structure of the probe. While the precise probe has been sufficiently described, (i.e., consisting of SEQ ID NO: ) regions 5' or 3' to that of the probe cannot be envisioned by one of skill in the art. The instant fact pattern closely resembles that in *Ex parte Maizel*, 27 USPQ2d 1662 (BPAI 1992). In *Ex parte Maizel*, the claimed invention was directed to compounds which were defined in terms of function rather than sequence. The only disclosed compound in *Ex parte Maizel* was the full length, naturally occurring protein. The Board found that there was no reasonable correlation between the scope of exclusive right desired by Appellant and the scope of enablement set forth in the patent application. Even though Appellant in *Ex parte Maizel* urged that the biologically functional equivalents would consist of proteins having amino acid substitutions wherein the substituted amino acids have similar hydrophobicity and charge characteristics such that the substitutions are "conservative" and do not modify the basic functional equivalents of the protein, the Board found that the claims encompassed an unduly broad number of compounds. Such is the instant situation because the claims simply recite probes which are functionally capable of forming a hybrid with *T. vaginalis*, but not with *T. tenax*.

Finally, Applicants assert that the structural identities of the probes plus a

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functional requirement (hybridize to nucleic acid derived from *T. vaginalis* but not *T. tenax*) are set forth. However, while Applicants claims which recite probes "consisting of" a particular sequence are satisfied by such claim limitations, probes "comprising" or "having" these sequences fail to sufficiently describe the structure of the probes. Again, the structure of the probe will directly determine which DNA molecules it is capable of hybridizing too. However, by not describing the structure of the regions 5' or 3' beyond the specifically identified probe, Applicants specification is satisfied solely for the identified probe (i.e., consisting of).

The specification and claims do not indicate what distinguishing attributes are shared by the members of the genus. Thus, the scope of the claims includes numerous structural variants, and the genus is highly variant because a significant number of structural differences between genus members is permitted. Since the disclosure fails to describe the common attributes or characteristics that identify members of the genus, and because the genus is highly variant, "a probe, comprising a target binding region having the base sequence of SEQ ID NO: 1-4" alone is insufficient to describe the genus. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus. Thus, applicant was not in possession of the claimed genus.

Adequate written description requires more than a mere statement that it is part of the invention and a reference to a potential method of isolating it. See *Fiers v. Revel*, 25 USPQ 2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. V. Chugai Pharmaceutical Co.*

Lts., 18 USPQ2d 1016.

Applicants are directed to the Revised Interim Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, 1 "Written Description" Requirement, Federal Register, Vol. 64, No. 244, pages 71427-71440, Tuesday December 21, 1999.

For reasons of record as well as the reasons set forth above, this rejection is maintained.

2. The rejection of claims 1-19, 21-38 and 77-80 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is maintained as applied to newly added claims 81-93, 95-110, and 112-131.

Applicants are asserting that it is within the capabilities of those skilled in the art to establish stringent conditions without undue experimentation. Applicants further assert that several claims set forth particular temperature and salt conditions.

Applicants arguments have been fully considered but are not found to be persuasive.

Applicants are asserting that it is within the capabilities of those skilled in the art to establish stringent conditions without undue experimentation. However, the question remains what are those conditions? What one individual considers stringent conditions another can consider non-stringent. The scientific community has not agreed upon one set of conditions that can be considered stringent or non-stringent. Accordingly, the metes and bounds of the claimed invention cannot be determined.

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Furthermore, Applicants assert that several claims set forth particular temperature and salt conditions. However, while this is a step in the right direction, stringency of hybridization is controlled by the wash step. Applicants "stringent hybridization" conditions do not set forth what kind of chemical conditions are employed for this all important step. Accordingly, the metes and bounds of what will remain hybridized cannot be determined.

For reasons of record as well as the reasons set forth above, this rejection is maintained.

3. The rejection of claims 1-19, 21-38 and 77-80 under 35 U.S.C. 112, second paragraph, as being vague and indefinite in the use of the phrase derived from is withdrawn.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. The rejection of claims 1-19, and 77 under 35 U.S.C. 102(b) as being anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Mayta et al is withdrawn in view of Applicants amendment.

The following new grounds of rejection are applied to the newly added claims:

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 81, 90, 95 and 109 are rejected under 35 U.S.C. 102(b) as being anticipated by Gunderson et al (J. Eukaryotic Microbiology Vol 42 (4), pp 411-415, 1995).

The claims are directed to a detection probe for use in determining the presence of *T. vaginalis*, said probe comprising a target binding region having the base sequence of SEQ ID NO: 1, 2, 3, or 4, wherein said probe forms a hybrid stable for detection with nucleic acid derived from *T. vaginalis* but not from *T. tenax* under stringent conditions.

Gunderson et al disclose of *T. vaginalis* 16S-like rRNA genes. Gunderson et al further disclose of a nucleotide sequence having a 100% match with SEQ ID NO: 1 of the instant invention. (See nucleotides 1162-1193 of Gunderson et al; sequence alignment enclosed). Gunderson et al further disclose of a sequence having 100% identity with SEQ ID NO: 17 of the instant invention.

Note the phrase "for use in determining the presence" is merely an intended use of the claimed molecule, and therefore carries no patentable weight.

Since the Patent office does not have the facilities for examining and comparing Applicants product with the product of the prior art reference, the burden is on Applicants to show an unobvious distinction between the material structural and functional characteristics of the claimed product and the product of the prior art. *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977).

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Navarro whose telephone number is (571) 272-0861.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on (571) 272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Mark Navarro  
Primary Examiner  
June 14, 2007

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*SE & ID # 1*

## RESULT 12

TVU17510

LOCUS TVU17510 1574 bp DNA linear INV 30-NOV-1995

DEFINITION Trichomonas vaginalis 16S-like rRNA gene.

ACCESSION U17510

VERSION U17510.1 GI:687613

## KEYWORDS

SOURCE Trichomonas vaginalis

ORGANISM Trichomonas vaginalis

Eukaryota; Parabasalidea; Trichomonada; Trichomonadida;  
Trichomonadidae; Trichomonadinae; Trichomonas.

REFERENCE 1 (bases 1 to 1574)

AUTHORS Gunderson,J., Hinkle,G., Leipe,D., Morrison,H.G., Stickel,S.K.,  
Odelson,D.A., Breznak,J.A., Nerad,T.A., Muller,M. and Sogin,M.L.TITLE Phylogeny of trichomonads inferred from small-subunit rRNA  
sequences

JOURNAL J. Eukaryot. Microbiol. 42 (4), 411-415 (1995)

PUBMED 7620466

REFERENCE 2 (bases 1 to 1574)

AUTHORS Hinkle,G.

TITLE Direct Submission

JOURNAL Submitted (22-NOV-1994) Gregory Hinkle, Marine Biological  
Laboratory, Program in Molecular Evolution, Water Street, Woods  
Hole, MA 02543, USA

## FEATURES Location/Qualifiers

source 1..1574  
/organism="Trichomonas vaginalis"  
/mol\_type="genomic DNA"  
/db\_xref="taxon:5722"rRNA 1..1574  
/product="16S-like ribosomal RNA"

## ORIGIN

Query Match 100.0%; Score 32; DB 13; Length 1574;  
Best Local Similarity 100.0%; Pred. No. 0.00092;  
Matches 32; Conservative 0; Mismatches 0; Indels 0; Gaps 0;

Qy 1 GCCGAAGTCCTTCGGTAAAGTTCAATTGGG 32



Db 1162 GCCGAAGTCCTTCGGTAAAGTTCAATTGGG 1193